DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Duerr Dental AG
% Ms. Suzanne Lucas
Quality Specialist, Regulatory Affairs
Air Techniques, Inc.
1295 Walt Whitman Road
MELVILLE NY 11747

February 22, 2016

Re: K143290
Trade/Device Name: DBSWIN and VistaEasy Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 4, 2016
Received: February 8, 2016

Dear Ms. Lucas:

This letter corrects our substantially equivalent letter of February 18, 2016.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

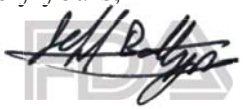
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143290

Device Name
DBSWIN and VistaEasy Imaging Software

Indications for Use *(Describe)*
DBSWIN and VistaEasy imaging software are intended for use by qualified dental professionals for windows based diagnostics. The software is a diagnostic aide for licensed radiologists, dentists and clinicians, who perform the actual diagnosis based on their training, qualification, and clinical experience. DBSWIN and VistaEasy are clinical software applications that receive images and data from various imaging sources (i.e., radiography devices and digital video capture devices) that are manufactured and distributed by Duerr Dental and Air Techniques. It is intended to acquire, display, edit (i.e., resize, adjust contrast, etc.) and distribute images using standard PC hardware. In addition, DBSWIN enables the acquisition of still images from 3rd party TWAIN compliant imaging devices (e.g., generic image devices such as scanners) and the storage and printing of clinical exam data, while VistaEasy distributes the acquired images to 3rd party TWAIN compliant PACS systems for storage and printing.

DBSWIN and VistaEasy software are not intended for mammography use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

General Information

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Date Prepared: February 4, 2016

Device

Name of Device:	DBSWIN and VistaEasy Imaging Software
Common or Usual Name:	Radiological Image Processing System
Classification Name:	Picture archiving and communications system (21 CFR 892.2050)
Regulatory Class:	II
Primary Product Code:	LLZ

Predicate Device

Manufacturer	Product Name	510(k) No.
Televere Systems	Visix Imaging	K082623

Device Description

DBSWIN and VistaEasy imaging software is an image management system that allows dentists to acquire, display, edit, view, store, print, and distribute medical images. DBSWIN and VistaEasy software runs on user provided PC-compatible computers and utilize previously cleared digital image capture devices for image acquisition.

VistaEasy is included as part of DBSWIN. It provides additional interfaces for Third Party Software. VistaEasy can also be used by itself, as a defeatured version of DBSWIN.

Indication for Use

DBSWIN and VistaEasy imaging software are intended for use by qualified dental professionals for windows based diagnostics. The software is a diagnostic aide for licensed radiologists, dentists and clinicians, who perform the actual diagnosis based on their training, qualification, and clinical experience. DBSWIN and VistaEasy are clinical software applications that receive images and data from various imaging sources (i.e., radiography devices and digital video capture devices) that are manufactured and distributed by Duerr Dental and Air Techniques. It is intended to acquire, display, edit (i.e., resize, adjust contrast, etc.) and distribute images using standard PC hardware. In addition, DBSWIN enables the acquisition of still images from 3rd party TWAIN compliant imaging devices (e.g., generic image devices such as scanners) and the storage and printing of clinical exam data, while VistaEasy distributes the acquired images to 3rd party TWAIN compliant PACS systems for storage and printing.

DBSWIN and VistaEasy software are not intended for mammography use.

Comaptible Hardware Devices

The DBSWIN System can record images from any of the Duerr Dental image acquisition devices listed below.

Common Name	Trade Name	FDA 510(k)
Intraoral Camera	VistaCam iX Proof	K150672
	VistaCam iX Cam	n/a
	VistaCam iX Macro	n/a
Extraoral Radiography X-Ray	VistaPano S	K130585
	ProVecta S-Pan[1]	
Phosphor Plate Scanner	ScanX Swift[2]	K013893

[1] Identical to VistaPano S from Duerr Dental
[2] Identical to VistaScan Mini from Duerr Dental

Technological Characteristics

DBSWIN and VistaEasy are software devices that do not come in contact with patients, and do not control life sustaining devices. DBSWIN and VistaEasy imaging software have the same main technological characteristics as the predicate devices.

Predicate Similarities and Technological Comparison:

DBSWIN and VistaEasy imaging software by Duerr Dental AG are two software components that are substantially equivalent to Visix Imaging PACS software applications that have similar indications for use, functionality, performance, and features as shown in the following comparison Table.

Parameters	DBSWIN/VistaEasy Duerr AG K143290	Visix Imaging Televere Systems K082623
Indications for Use	DBSWIN and VistaEasy imaging software are intended for use by qualified dental professionals for windows based diagnostics. The software is a diagnostic aide for licensed radiologists, dentists and clinicians, who perform the actual diagnosis based on their training, qualification, and clinical experience. DBSWIN and VistaEasy are clinical software applications that receive images and data from various imaging sources (i.e., radiography devices and digital video capture devices) that are manufactured and distributed by Duerr Dental and Air Techniques. It is intended to acquire, display, edit (i.e., resize, adjust contrast, etc.) and distribute images using standard PC hardware. In addition, DBSWIN enables the acquisition of still images from 3rd party TWAIN compliant imaging devices (e.g., generic image devices such as scanners) and the storage and printing of clinical exam data, while VistaEasy distributes the acquired images to 3rd party TWAIN compliant PACS systems for storage and printing. DBSWIN and VistaEasy software are not intended for mammography use.	Visix Imaging is a clinical software application that receives images and data from various imaging sources (e.g., radiographic devices, digital video capture devices, and generic image devices such as scanners). Visix Imaging is intended to acquire, display, edit (e.g., resize, adjust contrast, annotate, etc.), review, store, print, and distribute, images, plus store clinical notes in the form of annotations and measurements, using standard PC hardware. Visix Imaging is currently intended for dental use. It is not intended for mammography use.
Patient Management*	Yes	Yes
Image Management	Yes	Yes

Parameters	DBSWIN/VistaEasy Duerr AG K143290	Visix Imaging Televere Systems K082623
Acquire Images		
X-ray (i.e., Phosphor Plate, Digital Panoramic)	Yes	Yes
Laser Fluorescence Caries Detection Aid	Yes	Yes
Video	Yes	Yes
Photos	Yes	Yes
Documents	Yes	Yes
Import*	Yes	Yes
Display Images	Yes	Yes
Save/Store Images*	Yes	Yes
Produce Reports*	Yes	Yes
Print/Export Images*	Yes	Yes

Parameters	DBSWIN/VistaEasy Duerr AG K143290	Visix Imaging Televere Systems K082623
Enhance Images		
Brightness	Yes	Yes
Contrast	Yes	Yes
Colorize*	Yes	Yes
Crop	Yes	Yes
Rotate	Yes	Yes
Zoom In/Out	Yes	Yes
Invert*	Yes	Yes
Sharpen*	Yes	Yes
Measure*	Yes	Yes
Over/Under Exposure	Yes	Yes
Annotate*	Yes	Yes
Run on standard PC-compatible computers	Yes	Yes

*Features unavailable on VistaEasy.

Clinical and Non-Clinical Testing include:

- DBSWIN/VistaEasy was developed in compliance with the harmonized standard of IEC 62304 for medical device software life cycle requirements.
- DBSWIN product has been in sales and distribution in the European dental market for over 15 years serving and performing the same intended use, functionality, and hardware compatibility interfaces with 3rd party software.
- Bench testing, effectiveness, and functionality were successfully conducted and verified between DBSWIN and VistaEasy, and image capture devices.
- DBSWIN is DICOM compliant.
- Risk Analysis based design development and design reviews were conducted.
- Full functional software cross check testing was performed.

Minimum System Requirement for Computer Imaging Systems and Differences between DBSWIN and VistaEasy:

Hardware Requirements	DBSWIN/ VistaEasy
Platform	Microsoft Windows XP Professional, 32 bit, SP 3, Microsoft Windows 7, 32 bit (from Home Premium), Microsoft Windows 7, 64 bit (from Home Premium), Microsoft Windows 8, 64 bit (not Windows RT), Microsoft Windows Server 2012
CPU	≥ Intel Pentium IV compatible, 1.4 GHz, ≥ Intel Core i3
RAM	≥ 1GB (2GB recommended), ≥ 4 GB
Drive	DVD-ROM
Hard Disk	Workstation (without database) ≥50 GB
Data Backup[1]	Daily data back up
Interface	Ethernet ≥ 100 Mbit
Diagnostic Monitor	SVGA ≥ 17", ≥ 1024 x 768 pixel, 24/32 bit color depth
Resolution /Graphics	≥ 1024 x 768
Run on standard PC-compatible computers	Yes

4 - Daily data backup is not required for VistaEasy since it does not allow the storage of data.

Summary

Duerr Dental AG's DBSWIN and VistaEasy imaging software have demonstrated to perform as intended, and comply with industry compliance standard.

Conclusions

DBSWIN and VistaEasy Imaging software, and predicate devices are substantially equivalent in the areas of technical characteristics, function, intended use, and performance.

DBSWIN and VistaEasy Imaging software, and predicate devices are substantially equivalent with respect to safety and effectiveness to existing legally marketed devices and Picture Archiving and Communications Systems (PACS).